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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,288

04/13/2005

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/528,288</p>	<p>Applicant(s) JOSEPH ET AL.</p>	
	<p>Examiner Bradley L. Sisson</p>	<p>Art Unit 1634</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1,3-7,9-12,15-19,22-28 and 39.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Bradley L. Sisson/
Primary Examiner
Art Unit: 1634

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 8 and 21, and the rejection of claims under 35 USC 112, first paragraph, to the extent the rejection is directed to detection of a process and not a product. However, the rejection of claims under 35 USC 112, first paragraph, is maintained as it relates to detection of a product.

Continuation of 11. does NOT place the application in condition for allowance because: At page 7 of the response filed 19 September 2008, hereinafter the response, applicant's representative asserts that claims 1 and 15 are the only independent claims in the instant application. It is noted, however, that claim 39 is still pending and is also independent. At page 7 of the response applicant asserts:

"With respect to claim 1, the claimed invention overcomes several of the time-consuming steps associated with prior art detection methodologies and specifically teaches the ability to detect an elongated oligonucleotide without the need for separation methods such as fluorescence polarization (page 7, lines 7-27) where the fluorescence polarization signal is indicative of size of the oligonucleotide and as such the labeled oligonucleotide signal changes after the oligonucleotide has been lengthened to form an elongated oligonucleotide. Based on file highly detailed example provided in the specification as filed as Example 2, Applicant respectfully submits that one of skill in the art would be able to detect the elongated oligonucleotide as per claim 1 based on a greater than 15% increase in fluorescence polarization (301 mP versus 258 mP for reference)."

It is noted with particularity that claims 1, 7, and 9-11 place no restriction on the label and clearly are not limited to the use of a fluorescent label, much less the manner in which a signal is detected.

It is further noted that while claims 4-6, 15-19, 22-28, and 39 do require a fluorescent label, the manner of measuring and detecting a signal is not limited. And while claims 12 and 28 do recite "fluorescence polarization," said claims also teach that "the step of assaying the labeled oligonucleotide" could also be fluorescence intensity as well as fluorescence resonance energy transfer, and not fluorescence polarization. While claims are to be read as broadly as is reasonably possible, limitations found in the disclosure and/or in applicant's remarks are not read into the claims.

Page 6, first full paragraph, of the specification teaches that the method preferably includes the removal of unreacted detectable moieties from the reaction mixture. Such a method step is reasonable, especially when one could be simply looking for the presence, or intensity of a signal. However, the claims do not recite such a limitation.

At page 7, second paragraph, of the specification, applicant teaches: "Since a larger fluorescent molecule rotates more slowly than a smaller fluorescent molecule, changes in fluorescence polarization in a reaction including a fluorescently labeled oligonucleotide are indicative of changes in size of the oligonucleotide or its binding to another molecule." It is noted that the aspect of primer-dimerization, non-specific binding, etc. would all generate situations where the labeled primer would be bound to another molecule and would appear considerably larger. The specification is silent as to how one would be able to differentiate between two identical signals when one is the result of the intended elongated oligonucleotide (primer) and the other is the result of the labeled oligonucleotide binding to other molecules and appearing equally large, but has not undergone any elongation.

It is further noted that applicant's representative makes assertions at pages 7-9 as to what one of skill in the art would have understood or been capable of doing. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145. "Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration."

With regard to Example 2 of the disclosure, found at pages 10-11 of the disclosure, it is noted that the specification does not teach the nucleotide sequence of the primer, the nucleotide of the target/template, nor disclose the number of nucleotides that the primer/oligonucleotide is being elongated. Accordingly, the generation of a polarization number indicative of a change in length is not informative as to there having been a mispriming, misincorporation of a nucleotide, triplex formation, and/or premature termination of the elongation reaction- all of which are erroneous results, yet cannot be discerned by the claimed method.

In view of the above remarks, and in the absence of convincing evidence to the contrary, claims 1, 3-7, 9-12, 15-19, 22-28, and 39 remain rejected under 35 USC 112, first paragraph.

At page 11 of the response, applicant's representative directs attention to page 4, lines 10-12, of the disclosure as providing a definition for "oligonucleotide hybrid." It is noted that the definition provided at said citation is exemplary and not limiting. In support of this position, attention is directed to the clause "a hybridization reaction may include..." It is less than clear what else it "may" include. Accordingly, the metes and bounds cannot be readily determined. Accordingly, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 112, second paragraph, is maintained.